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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,371	08/13/2001	Fred H. Burbank	9619-1001	2284
7590 Edward J. Lynch Duane Morris LLP One Market Spear Tower Ste 2000 SAN FRANCISCO, CA 94105	03/22/2007		EXAMINER SZMAL, BRIAN SCOTT	
			ART UNIT 3736	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/929,371	BURBANK ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-25, 27, 28, 30, 32, 33, 40-44 and 47-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25, 27, 28, 30, 32, 33, 40-44 and 47-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/10/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2007 has been entered.

***Specification***

2. The abstract of the disclosure is objected to because the abstract exceeds 150 words. Correction is required. See MPEP § 608.01(b).

***Claim Objections***

3. Claim 32 is objected to because of the following informalities: The claim refers to cancelled Claim 31. Appropriate correction is required.

4. Claims 17, 21, 30, 40, 48, 50-55, 57 and 67 are objected to because of the following informalities: The claims disclose the use of "its" which renders the claims indefinite due to the fact that "its" is not clearly disclosed as to what "its" refers to in each of the claims. Appropriate correction is required.

***Allowable Subject Matter***

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5. The indicated allowability of claims 28 and 33 is withdrawn in view of the newly discovered reference(s) to McGuckin, Jr. (6,280,450 B1). Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 17, 21, 25, 27, 28, 48, 50-53, 55-57 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin, Jr. (6,280,450 B1).

McGuckin, Jr. discloses a breast surgery means and further discloses a shaft, a longitudinal axis, a distal end on the shaft; a tissue cutting surface on the distal end to facilitate advancement of the instrument through tissue to a target site; an elongated electrosurgical cutting element longitudinally disposed on a distal portion of the shaft proximal to the cutting surface on the distal end which is configured to receive RF energy from a source for severing the tissue specimen from the surrounding tissue; an encapsulating element which is secured to the distal portion of the shaft and which is configured to encapsulate the severed tissue specimen so the specimen may be withdrawn from the body in a single piece; the electrosurgical cutting element is

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actuatable between a retracted position and an extended position, and is rotatable about the longitudinal axis; a sheath axially movable between distal and proximal positions for selectively covering and uncovering the encapsulating element; a cutting element actuatable to cut tissue as the instrument is proximally withdrawn from the body. See Figures 1, 4 and 5; Column 5, lines 56-67; Column 6; Column 7, lines 1-14, in particular lines 31-44.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 18-20, 22-24, 58-60, 64-67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claims 17, 21, 50-53, 55 and 57 above, and further in view of Patterson et al (5,941,869).

McGuckin, Jr., as discussed above, disclose a means for removing tissue from the body through the use of an encapsulating element, but fail to disclose the encapsulating element comprises a band or a plurality of bands that are actuatable between a retracted position and an extended position; the electrosurgical cutting element comprises one of the encapsulating elements; the bands may be twisted for encapsulating the specimen; and the specimen is encapsulated as the electrosurgical element is rotated about the longitudinal axis.

Patterson et al disclose a means for removing tissue from the body and further disclose the encapsulating element comprises a band or a plurality of bands that are actuatable between a retracted position and an extended position; the electrosurgical cutting element comprises one of the encapsulating elements; the bands may be twisted for encapsulating the specimen; and the specimen is encapsulated as the electrosurgical element is rotated about the longitudinal axis. See Figures 11, 12 and 37-39; Column 12, lines 64-67; Column 13, lines 1-15 and 46-60; Column 16, lines 29-51; Column 18, lines 64-67; Column 19, lines 1-7; and Column 27, lines 4-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of McGuckin, Jr. to include the use of bands as the encapsulating element, as per the teachings of Patterson et al, since it would provide an alternative means of encapsulating the tissue prior to removal from the body.

10. Claims 30, 32, 33, 49, 54, 62 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) in view of Patterson et al (5,941,869).

McGuckin, Jr., as discussed above, disclose a means for removing tissue from a breast, including providing an instrument having an elongated shaft, a distal end, a longitudinal axis, at least one encapsulating element of the distal end and an axially disposed electrosurgical cutting element on the distal shaft portion; inserting the instrument to a target site; radially extending the electrosurgical cutting element; rotating the extended cutting element while the element is energized with RF energy to cut a specimen from surrounding tissue; withdrawing the encapsulated specimen from the

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body; and proximally withdrawing the instrument with the encapsulated specimen from the body, and including cutting tissue as the instrument is withdrawn. See Figures 1, 4 and 5; Column 5, lines 56-67; Column 6; Column 7, lines 1-14, in particular lines 31-44.

McGuckin, Jr., however fails to disclose radially extending the encapsulating element and rotating the element to encapsulate the specimen; the encapsulating element comprises a plurality of bands; and the device is disposable.

Patterson et al, as discussed above, disclose radially extending the encapsulating element and rotating the element to encapsulate the specimen; the encapsulating element comprises a plurality of bands; and the device is disposable. See Figures 11, 12 and 37-39; Column 12, lines 64-67; Column 13, lines 1-15 and 46-60; Column 16, lines 29-51; Column 18, lines 64-67; Column 19, lines 1-7; and Column 27, lines 4-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of McGuckin, Jr. to include the use of bands as the encapsulating element, as per the teachings of Patterson et al, since it would provide an alternative means of encapsulating the tissue prior to removal from the body.

11. Claims 40-44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. 6,280,450 B1) in view of Hassler, Jr. (5,445,142).

McGuckin, Jr., as discussed above, disclose a means for removing tissue from a breast, including an elongated shaft having a longitudinal axis, and proximal and distal ends; at least one element secured on the distal portion and configured to encapsulate the specimen; a distal portion of the shaft is provided with a tissue cutting member

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spaced proximally from the distal end of the shaft; the tissue cutting member has an extended position and a retracted position; the cutting member is arcuate in shape when expanded; and the cutting element is rotatable about the longitudinal axis of the shaft.

McGuckin, Jr., however fails to disclose a thin electrosurgical cutting element secured to the distal end of the elongated shaft having a blunt arcuate surface portion spaced distally from the distal end of the shaft; and the thin electrode is formed of conductive metallic material.

Hassler, Jr. discloses a surgical trocar with an electrosurgical distal tip and further disclose a thin electrosurgical cutting element secured to the distal end of the elongated shaft having a blunt arcuate surface portion spaced distally from the distal end of the shaft; and the thin electrode is formed of conductive metallic material. See Figures 8-10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal end of McGuckin, Jr. to include an electrosurgical cutting element, as per the teachings of Hassler, Jr., since it would provide a less traumatic means of accessing the target site. Even though Hassler, Jr. does not disclose an arcuate shaped cutting portion, the difference in shape of Hassler, Jr., in relation to the current application, is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).



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12. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. 6,280,450 B1) in view of Hassler, Jr. (5,445,142) as applied to claim 40 above, and further in view of Patterson et al (5,941,869).

McGuckin, Jr. and Hassler, Jr., as discussed above, disclose a means for penetrating and removing tissue, but fail to disclose the encapsulating element is configured to encapsulate the specimen by rotating the element about the longitudinal axis.

Patterson et al, as discussed above, disclose a means for removing tissue from the body, and further disclose the encapsulating element is configured to encapsulate the specimen by rotating the element about the longitudinal axis. See Figures 11, 12 and 37-39; Column 12, lines 64-67; Column 13, lines 1-15 and 46-60; Column 16, lines 29-51; Column 18, lines 64-67; Column 19, lines 1-7; and Column 27, lines 4-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of McGuckin, Jr. and Hassler, Jr. to include the use of an encapsulating element that is configured to encapsulate the specimen when rotated, as per the teachings of Patterson et al, since it would provide an alternative means of encapsulating the specimen prior to removal from the body.

### ***Response to Arguments***

13. Applicant's arguments with respect to claims 17-25, 27, 28, 30, 32, 33, 40-44 and 47-69 have been considered but are moot in view of the new ground(s) of rejection.

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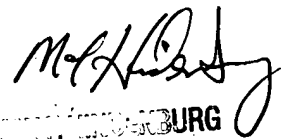
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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